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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,506 | 01/05/2005 | Heinz Von Der Kammer | P67785US1 | 6896 |

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| EXAMINER | |
|---|---|
| SHEN, WU CHENG WINSTON | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 01/29/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,506 | VON DER KAMMER ET AL. | |
| | Examiner | Art Unit | |
| | Wu-Cheng Winston Shen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This application 10/533,003 filed on Jan. 05, 2005 is a 371 of PCT/EP03/03626 filed on 04/08/2003 claims benefit of the provisional application 60/370,214 filed on 04/08/2002.

### *Election/Restriction*

1. Applicant's election with traverse of Group VIII, claim 14 (in part), drawn to a protein based assay for screening or testing for a modulator or a compound of neurodegenerative disease, in particular Alzheimer's disease, or related diseases or disorders of a substance of a translation product or a fragment or derivative of the translation product of a gene coding for a vault protein, the minor vault protein ADPRTL1, or a compound for inhibition of binding between a ligand and ADPRTL1 vault protein, in the reply filed on Nov. 15, 2006 is acknowledged. The traversal is on the ground(s) that the common special technical feature being use of the minor vault protein ADPRTL1 in a method involving diagnosis or treatment of neurodegenerative diseases --- not merely the minor vault protein ADPRTL1, itself, as alleged in the statement of restriction. The traversal is not found persuasive because methods comprising patentably distinct materials and steps involving screening, or modulation, or detection of ADPRTL1 DNA, or ADPRTL1 RNA or ADPRTL1 protein do not constitute a special technical feature.

Claims 1-13, 15-21, and 14 (regarding ADPRTL1 gene and transcription product of the ADPRTL1 gene) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

***Status of claims:*** Claim 14 (regarding translation product of ADPRTL1 gene) is currently under examination.

### *Claim Objections*

2. Claim 14 is objected to because of the following informalities: Recitation of non-elected subject matters: (i) ADPRTL1 gene and (ii) transcription product of ADPRTL1 gene. Appropriate correction is required.

### *Claim Rejection - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim

indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 14 recites the broad recitation *neurodegenerative diseases*, and the claim also recites in particular *Alzheimer's disease*, or related diseases or disorders, which is the narrower statement of the range/limitation.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the phrase "or related diseases or disorders *of one or more substances selected from the group consisting of*" fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear the phrase "*of one or more substances selected from the group consisting of*" is referring to a modulator or a neurodegenerative disease.

***Claim Rejection - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is directed to an assay for screening for a modulator of neurodegenerative disease, wherein the assay involves a translation product of a gene coding for a vault protein and/or a fragment, or derivative, or variant of a translation product of a gene coding for a vault protein.

With regard to the phrase "a gene coding for a vault protein and/or a fragment, or derivative, or variant of a translation product of a gene coding for a vault protein", the phrase encompasses any vault protein and/or a fragment, or derivative, or variant of a translation product of a gene coding for any vault protein.

The genes coding for a vault protein, variants, and fragments thereof encompassed within the genus of genes coding for a vault protein, variants, and fragments thereof, have not been disclosed. Based upon the prior art there is expected to be variation among the species of genes coding for vault proteins, because the sequence of the genes involved in coding for a vault protein would be expected to vary among individuals. The specification discloses amino acid sequences of human minor vault protein ADPRTL1 as SEQ ID NO: 2. There is no evidence on the record of a relationship between the structure of any vault protein sequences and the claimed SEQ ID NO: 2 sequences for other genes encoding vault proteins that would provide any reliable information about the structure of other vault proteins, variants, and fragments thereof, within the

genus. There is no evidence on the record that the asserted human minor vault protein ADPRTL1 sequences had a known structural relationship to any other vault protein sequences; the specification discloses only human minor vault protein ADPRTL1 as SEQ ID NO: 2 obtained from an undisclosed origin; the art indicated that there is variation between minor vault protein ADPRTL1 (as well as between other vault proteins) and their functions. The specification has not even disclosed the types of nucleic acid sequences encoding the human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 that the claimed human minor vault protein ADPRTL1 are with regard to their functions. There is no evidence of record that would indicate that any of the claimed variants and fragments of human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 that share high homology to human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 even have the biological activity of a minor vault protein ADPRTL1. In the absence of a functional assay it would not be possible to test variants of the claimed sequences for biological activity. Also with regard to the claimed allelic variants, the skilled artisan cannot envision the structure of such a variant because such variants are randomly produced in nature, and cannot be predicted from a known sequence. The specification does not teach any characteristics of an "allelic" variant that would distinguish it from a non-natural variant constructed by the hand of man. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because the human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 is not representative of the claimed genus. Consequently, since Applicant was in possession of only the human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 and since the art recognized variation among the species of the genus of a vault protein, variants, and fragments

thereof, the human minor vault protein ADPRTL1 disclosed in SEQ ID No: 2 was not representative of the claimed genus. Therefore, Applicant was not in possession of the genus of the genus of a vault protein, variants, and fragments thereof as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Rome et al., (Rome et al., PCT/US98/11348, WO 99/62547, listed in the IDS filed by the applicants).

It is noted that (i) minor vault protein ADPRTL1 is also known as VPARP, PHP5, or p193 (See line 4, second paragraph, page 3 of instant application), and (ii) neurodegenerative diseases, or *related diseases or disorders* recited in claim 14 of instant application are interpreted as *any disease related to any neurodegenerative disease*, which would encompass multidrug-resistant cancers because treatment of neurodegenerative diseases, which would include neuroectodermal tumors as the specification of instant application does not define what a neurodegenerative disease is, with multiple drugs might lead to the selection of multidrug

resistant cells, whose deregulation in proliferation, in turn, would result in multidrug-resistant cancers.

It is further noted that in this prior art rejection, claim 12 is interpreted as an assay for screening a modulator of neurodegenerative diseases, wherein the said modulator affects the level of the translation product of a ADPRTL1 gene and/or the activity of the translation product of a ADPRTL1 gene, wherein the screening comprises the recited steps (a)-(d).

Rome et al. teach purified human minor vault protein p193 or purified biologically active variants thereof, or a combination of purified human minor vault protein p193 and biologically active variants thereof are disclosed. A polynucleotide molecule encoding human minor vault protein p193, or the complementary DNA is also disclosed. Furthermore, Rome et al. teach a method of diagnosing and a method of treating patients with multidrug resistant cancer (See abstract, Rome et al., 1999).

More specifically, Rome et al., teach (i) a high affinity monoclonal antibody with immunoreacts with human minor vault protein p193 (claim 22, page 25), (ii) a method of diagnosing a patient with a multidrug-resistant cancer comprising the steps of (a) providing a sample of tissue or fluid from the patient, (b) determining the level of human minor vault p193 protein, which reads on contacting a cell with antibody against human minor vault protein p193, a control without contacting cell with the antibody against human minor vault protein p193, and comparing the levels human minor vault protein p193 with and without antibody (See lines 7-26, page 3; and claim 27, page 25, Rome et al., 1999).

It is further noted that Rome et al. also teach a method of treating a patient with multidrug-resistant cancer comprising the steps of (a) diagnosing a patient with multidrug-

resistant cancer according the method of diagnosing a patient with a multidrug-resistant cancer as recited in the previous paragraph, and (b) treating the patient comprising administering to the patient at least one anti-sense polynucleotide having affinity for a polynucleotide encoding p193, which reads on contacting a cell with anti-sense polynucleotide having affinity for a polynucleotide encoding p193, a control without anti-sense polynucleotide having affinity for a polynucleotide encoding p193, and comparing the biological activity levels of human minor vault protein p193 with and without anti-sense polynucleotide having affinity for a polynucleotide encoding p193 (See claims 29 and 31, page 26, Rome et al., 1999).

Thus, Rome et al. clearly anticipates claim 14 of instant invention.

***Conclusion***

7. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent

examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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